IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PRO PUBLICA, INC., Plaintiff , - against - **UNITED STATES FOOD AND DRUG ADMINISTRATION** Defendant.	Case No: 24-8712 **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF FOR VIOLATION OF THE FREEDOM OF INFORMATION ACT, 5 U.S.C. § 552 *et seq*.**

Plaintiff Pro Publica, Inc. ("ProPublica" or "Plaintiff"), by and through its undersigned attorneys, brings this action under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552 *et seq*., for declaratory, injunctive and other appropriate relief to compel the disclosures and release of documents from Defendant Food and Drug Administration ("FDA"). In support thereof, Plaintiff alleges as follows:

INTRODUCTION

1. Plaintiff ProPublica is an independent, nonprofit news organization that specializes in conducting in-depth investigative journalism. It believes that investigative journalism helps sustain our self-governing democracy because it publicizes critical facts that governments and powerful interests might prefer to keep hidden. ProPublica's staff remains dedicated to exposing corruption, informing the public about complex issues, and using the power of investigative journalism to spur reform. ProPublica seeks to report on the safety and availability of widely used generic drugs that are manufactured overseas.

2. Between April 24 and July 30, 2024, Plaintiff, through its Pulitzer Prize-winning reporters Debbie Cenziper, Patricia Callahan and Megan Rose, submitted four FOIA Requests to Defendant FDA for records regarding medications that are manufactured, sold and shipped to the United States by multinational generic drug manufacturers. The requested information would help doctors, pharmacists, patients and policymakers, who are currently investigating drug safety and availability issues in Congress, understand whether the FDA adequately protects the public from contaminated or ineffective drugs. See Exhibits A-D.

3. The FDA is responsible for protecting public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices. For years, the agency's own inspectors have documented dangerous manufacturing practices inside factories that are entrusted with producing sterile injectables and other drugs for infants, children, the elderly, cancer patients, diabetics, veterans and the wider public. These well- publicized failures include unsanitary equipment, key ingredients that are ineffective, impure, or laced with cancer-causing substances, and fraudulent testing records that cover up how often drugs fail internal quality tests.

4. The Freedom of Information Act "focuses on the citizens' right to be informed about 'what their government is up to,'" by requiring the release of "[o]fficial information that sheds light on an agency's performance of its statutory duties." *DOJ v. Reporters Comm. for Freedom of the Press*, 489 U.S. 749, 750, 773 (1989) (citation omitted). "[D]isclosure, not secrecy, is the dominant objective" of FOIA. *Dep't of Interior v. Klamath Water Users Protective Ass'n*, 532 U.S. 1, 8 (2001) (internal quotation marks and citations omitted).

5. Defendant FDA has failed to comply with its obligations under FOIA. As of the date of this filing, Defendant has not issued a determination on any of Plaintiff's Requests and has failed to produce a single document related to these four FOIA requests.

6. Plaintiff brings this action to compel Defendant to immediately process and release to Plaintiff all responsive records that it has unlawfully withheld.

PARTIES

7. Plaintiff ProPublica's mission is to expose abuses of power and betrayals of the public trust by government, business, and other institutions, using the moral force of investigative journalism to spur reform through the sustained spotlighting of wrongdoing. ProPublica is an independent, nonprofit newsroom that produces investigative journalism with moral force. It digs deep into important issues, shining a light on abuses of power and betrayals of public trust — and it sticks with those issues as long as it takes to hold power to account. With a team of more than 150 editorial staffers, ProPublica covers a range of topics including government and politics, business, criminal justice, the environment, education, health care, immigration, and technology. It focuses on stories with the potential to spur real-world impact. Among other positive changes, its reporting has contributed to the passage of new laws; reversals of harmful policies and practices; and accountability for leaders at local, state and national levels. ProPublica is a Delaware 501(c)(3) corporation headquartered in New York, New York.

8. Defendant Food and Drug Administration is a federal regulatory agency in the Department of Health and Human Services and is an "agency" within the meaning of 5 U.S.C. § 552(f)(1). FDA has possession and control over the documents and information requested by Plaintiff.

JURISDICTION AND VENUE

9. This Court has both subject matter jurisdiction over this action and personal jurisdiction over the parties pursuant to 5 U.S.C. § 552(a)(4)(B), 5 U.S.C. §§ 701-706, and 28 U.S.C. § 1331.

10. Venue in the Southern District of New York is proper under 5 U.S.C. § 552(a)(4)(B) because ProPublica has its principal place of business in New York City and because ProPublica's FOIA Requests to FDA were made from the City and County of New York, within this District.

FACTUAL BACKGROUND

11. The Food and Drug Administration is an agency in the Department of Health and Human Services. It exists to ensure the safety and effectiveness of medicines, medical devices, biologics, cosmetics, tobacco and food. Its mission is to promote and protect public health and, in service of this worthy goal, it has more than 18,000 employees working in all 50 states and internationally.[1]

12. Nearly 60 percent of the factories making drugs for U.S. consumers are located overseas, spread across several thousand facilities in India, China and other countries.[2] While these facilities sell billions of capsules, tablets and injectable medications in the United States, the FDA for years has documented serious breakdowns in companies that manufacture them, including systemic failures that can harm or kill people. Last year, for example, the U.S. Centers for Disease Control and Prevention reported that tainted eye drops made in India killed four

[1] "About FDA" from FDA's website, https://www.fda.gov/about-fda/.

[2] Statement of Director of Health Care, FDA, Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives, Feb. 6, 2024, available at GAO-24-107359, DRUG SAFETY: FDA Has Faced Persistent Challenges Overseeing Foreign Drug Manufacturing.

Americans, forced some to have their eyeballs removed and blinded others.[3] In the wake of reports like these, lawmakers have held a series of hearings to investigate drug safety and address the ongoing dangers created by importing drugs from offshore facilities that routinely violate good manufacturing practices.

13. The Requests seek emails between key FDA officials and drug companies that will likely shed light on how the agency oversees this powerful industry. Just as critically, the Requests also seek the locations of where drugs are made so that the public is aware of the origins of the vitally important medicines it relies on, and so that those facilities can be properly scrutinized.

14. The need to uncover this information is critical. The FDA has made available public inspection reports that describe unsafe manufacturing practices, but it inexplicably redacted the names of the drugs made in those factories – meaning that Americans (including pharmacists, doctors, hospital systems, policy makers) cannot see for themselves which drugs may have been made in unsafe facilities.

15. But nothing in the law in any way limits the ability of the FDA to disclose where finished drugs were manufactured. In fact, this information is routinely released *by the FDA itself*. One such agency report, called an "import alert," in many cases publicly discloses where specific drugs were made.[4] In addition, some offshore drug manufacturers, like Sun Pharmaceutical Industries, voluntarily disclose this information by printing it on the labels of

[3] "Outbreak of Extensively Drug-resistant Pseudomonas aeruginosa Associated with Artificial Tears," U.S. Centers for Disease Control and Prevention, website updated March 21, 2023.

[4] See Import Alert 66-40, available at https://www.accessdata.fda.gov/cms_ia/importalert_189.html.

their products.[5] The federal government further publicizes this information through the NIH's DailyMed database, which publishes drug label information and DUNS manufacturing numbers that can be cross-referenced with an FDA drug establishment's database to identify a drug's manufacturing location.[6] The public is not required to painstakingly cross-reference databases for thousands of generic drugs, when the FDA has records containing these details at its fingertips.

16. There is a significant public interest in the disclosure of the information ProPublica seeks. Former FDA officials, members of Congress and a high-profile government task force have pushed for this data to be disclosed to help doctors, pharmacists, hospitals, healthcare systems, and government agencies (the Department of Defense, Veterans Affairs and the Centers for Medicare and Medicaid Services) identify potentially tainted drugs.[7] The prompt release of this data would also help these same entities better anticipate potential drug shortages caused by natural disasters, supply chain disruptions and other events.[8] The disclosure of this information is also likely to contribute significantly to public understanding of the operations or activities of the federal government, and the role of the FDA in regulating drugs imported into the U.S.

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[5] See Sun Pharma website, Products, Medication Guides showing manufacturer, available at https://sunpharma.com/usa/products/.

[6] DailyMed is available at https://dailymed.nlm.nih.gov/dailymed/spl-resources-all-drug-labels.cfm, and the FDA's Drug Establishments Current Registration Site is available at https://www.fda.gov/drugs/drug-approvals-and-databases/drug-establishments-current-registration-site.

[7] "NASEM report: FDA should disclose drug and device manufacturing information", Regulatory News, Mar. 4, 2022, available at NASEM report: FDA should disclose drug and device manufacturing information | RAPS.

[8] "FDA's Role in the Medical Product Supply Chain and Considerations During COVID-19", Report by Congressional Research Service, Sept. 1, 2020, available at FDA's Role in the Medical Product Supply Chain and Considerations During COVID-19 (congress.gov).

PLAINTIFF'S FIRST FOIA REQUEST (2024-3985)

17. Plaintiff filed its first FOIA Request to Defendant FDA on April 24, 2024. *See* Exhibit A (the "First Request").

18. The First Request sought emails sent or received by former Director of the FDA's Center for Drug Evaluation and Research Janet Woodcock, from January 1, 2022 to December 31, 2023, containing certain terms: import alert, red list, drug shortage, import ban, unannounced inspection[s], or emails containing both "India" and "inspection." *See* Exhibit A.

19. Plaintiff sought expedited processing pursuant to 5 U.S.C. § 552(a)(6)(E). ProPublica is an organization primarily engaged in disseminating information. Dissemination of accurate, current information about topics related to drug safety is crucial to ProPublica's mission to inform the public about matters concerning federal government activity. ProPublica will use the materials to publish critical public health information that could impact the lives of millions of Americans. Plaintiff explained there is an urgency to the Request because members of Congress, government watchdog groups, and the news media have recognized that the safety of drugs manufactured abroad is a pressing and ongoing national health concern.

20. Plaintiff also sought a fee waiver pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that disclosure of the requested records was in the public interest since disclosure was likely to contribute "significantly to public understanding of government operations and activities," and that ProPublica has no commercial interest in the records requested. *See* Exhibit A. ProPublica further stated that it qualified for a fee waiver because of its role as a news organization.

21. On May 1, 2024, FDA acknowledged the First Request and assigned it number 2024-3985. *See* Exhibit B. FDA denied expedited processing of the Request on May 6, 2024. *See* Exhibit C.

22. On June 5, 2024, Plaintiff filed an administrative appeal of the denial of expedited processing. FDA acknowledged the appeal on June 7, 2024, and affirmed the denial of expedited processing on October 22, 2024. *Id.*

23. Defendant's response was due on May 22, 2024 (*i.e.*, 20 business days from the date of the First Request). The FDA did not invoke an extension but, had it done so, its response would have been due within 30 business days, on June 6, 2024.

24. As of this date, Plaintiff has received no substantive response to its First Request, and the FDA has constructively denied Plaintiff's request in violation of FOIA.

PLAINTIFF'S SECOND FOIA REQUEST (2024-5491)

25. On June 13, 2024, ProPublica filed a second FOIA request with the FDA. *See* Exhibit D.

26. In a phone call on June 14, 2024, FDA FOIA Officer Sara Ashton explained to ProPublica Reporter Callahan how the FDA retrieves emails and suggested a narrowing of the request for a more timely release. Callahan took Ashton's suggestion. ProPublica revised the Second Request and resubmitted it on June 20, 2024. *See* Exhibit D (the "Second Request"). It sought emails: 1) sent or received by certain FDA employees (Janet Woodcock, Francis Godwin, Valerie Jensen, Michael Chasev, Alonza Cruse, Patrizia Cavazzoni, Emily Thakur, or Ganesh Joshi), 2) between the dates of January 1, 2020 and the date the Request is fulfilled, 3) that include the word "Sun Pharma", and 4) that also include any of the following terms: import refusal, import alert, red list, green list, shortage[s], DWPE, exclude or exclusion or excluded, exempt or exemption or exempted, warning letter[s], GMP, carve out[s], Gujarat, Halol, or 3002809586.[9]

[9] The FDA has in the past released warning letters, exceptions and import alerts. ProPublica does not believe these are subject to Exemption 4. But, to avoid litigation over the scope of the deliberative process privilege, ProPublica is willing to narrow the Second Request to only emails

27. ProPublica sought expedited processing pursuant to 5 U.S.C. § 552(a)(6)(E). ProPublica is an organization primarily engaged in disseminating information. Dissemination of accurate, current information about topics related to drug safety is crucial to ProPublica's mission to inform the public about matters concerning federal government activity. ProPublica will use the materials to publish critical public health information that could impact the lives of millions of Americans. Plaintiff explained there is an urgency to the Request because members of Congress, government watchdog groups, and the news media have recognized that the safety of drugs manufactured abroad is a pressing and ongoing national health concern.

28. Plaintiff also sought a fee waiver pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that disclosure of the requested records was likely to contribute "significantly to public understanding of government operations and activities," and that ProPublica has no commercial interest in the records requested. *See* Exhibit D. ProPublica further stated that it qualified for a fee waiver because of its role as a representative of the news media.

29. On June 21, 2024, Defendant sent an acknowledgment assigning the Second Request case number 2024-5491. *See* Exhibit E. FDA denied Plaintiff's request for expedited processing on June 25, 2024. ProPublica appealed the denial on June 28, 2024, and that appeal was denied on October 22, 2024. *See* Exhibit F.

30. Defendant's response was due on July 19, 2024 (*i.e.*, within 20 business days of receipt of the Second Request). The FDA did not invoke an extension but, had it done so, its response would have been due within 30 business days, on August 2, 2024.

31. As of this date, Plaintiff has received no substantive response to its Second Request, and the FDA has constructively denied Plaintiff's request in violation of FOIA.

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involving individuals outside the FDA during any pre-decisional period prior to Dec. 8, 2022.

PLAINTIFF'S THIRD FOIA REQUEST (2024-5682)

32. On June 25, 2024, ProPublica filed a third FOIA request with the FDA. *See* Exhibit G (the "Third Request"). The Third Request sought four categories of information (name of manufacturer, name of drug, location of manufacturing facility, and ANDA number) for all active ANDAs for generic drugs.[10] This information is contained in the ANDA application and is maintained in post-approval supplements that manufacturers file with the FDA whenever the manufacturing facility location changes.

33. ProPublica sought expedited processing pursuant to 5 U.S.C. § 552(a)(6)(E). ProPublica is an organization primarily engaged in disseminating information. Dissemination of accurate, current information about topics related to drug safety is crucial to ProPublica's mission to inform the public about matters concerning federal government activity. ProPublica will use the materials to publish critical public health information that could impact the lives of millions of Americans. Plaintiff explained there is an urgency to the Request because members of Congress, government watchdog groups, and the news media have recognized that the safety of drugs manufactured abroad is a pressing and ongoing national health concern.

34. Plaintiff also sought a fee waiver pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that disclosure of the requested records was in the public interest since disclosure was likely to contribute significantly to public understanding of government operations and activities," and that ProPublica has no commercial interest in the records requested. *See* Exhibit G. ProPublica further stated that it qualified for a fee waiver because of its role as a news organization. *Id.*

[10] "ANDA" is an acronym for "Abbreviated New Drug Application" and refers to the six-digit number assigned by the FDA to each application for approval to market a generic drug in the United States.

35. The FDA denied Plaintiff's request for expedited processing on July 5, 2024. *See* Exhibit H. ProPublica appealed the denial on July 11, 2024, but the appeal is still pending.

36. On July 30, 2024, ProPublica amended its Third Request. *See* Exhibit G.[11] The amended Third Request sought four categories of information (name of manufacturer, name of drug, location of manufacturing facility, and ANDA number) for all active ANDAs for generic drugs. This information is contained in the ANDA application. The amended Third Request also seeks the most current information, which is maintained in post-approval supplements that manufacturers file with the FDA if the manufacturing facility location changes.

37. Defendant's response was due within 20 business days of receipt of the Third Request, on August 27, 2024. The FDA did not invoke an extension but, had it done so, its response would have been due within 30 business days, on September 11, 2024.

38. As of this date, Plaintiff has received no substantive response to its Third Request, and the FDA has constructively denied Plaintiff's request in violation of FOIA.

PLAINTIFF'S FOURTH FOIA REQUEST (2024-5795)

39. On July 1, 2024, Plaintiff filed a Fourth FOIA Request with the FDA. *See* Exhibit I. The Fourth Request sought all communications sent to or received by email address drugshortages@fda.hhs.gov, between the dates of January 1, 2020, and the date the Request is fulfilled, that also include the words "Sun Pharma."

40. ProPublica sought expedited processing pursuant to 5 U.S.C. § 552(a)(6)(E). ProPublica is an organization primarily engaged in disseminating information. Dissemination of accurate, current information about topics related to drug safety is crucial to ProPublica's mission

[11] The Third Request was modified by adding the paragraph that appears in bold in Exhibit G, which clarified certain details pertaining to the scope of the Third Request.

to inform the public about matters concerning federal government activity. ProPublica will use the materials to publish critical public health information that could impact the lives of millions of Americans. Plaintiff explained there is an urgency to the Request because members of Congress, government watchdog groups, and the news media have recognized that the safety of drugs manufactured abroad is a pressing and ongoing national health concern.

41. Plaintiff also sought a fee waiver pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that disclosure of the requested records was in the public interest since disclosure was likely to contribute "significantly to public understanding of government operations and activities," and that ProPublica has no commercial interest in the records requested. *See* Exhibit I. ProPublica further stated that it qualified for a fee waiver because of its role as a news organization.

42. On July 2, 2024, Defendant sent Plaintiff an acknowledgment assigning the Fourth Request case number 2024-5795. *See* Exhibit J. FDA denied the request for expedited processing. ProPublica appealed the denial on July 11, 2024, but the FDA denied that appeal on October 22, 2024. *See* Exhibit F.

43. Defendant's response was due within 20 business days of receipt of the Fourth Request, on July 30, 2024. The FDA did not invoke an extension but, had it done so, its response would have been due within 30 business days, on August 13, 2024.

44. As of this date, Plaintiff has received no substantive response to its Fourth Request, and the FDA has constructively denied Plaintiff's request in violation of FOIA.

THE FDA'S FAILURE TO TIMELY RESPOND TO THE REQUESTS

45. At the time of filing this Complaint, the FDA has not responded to any of the Requests. Plaintiff has not received the required documentation from the FDA; nor has it received any responsive records or any other substantive reply to its Requests.

46. Despite its clear obligation under FOIA, Defendant has not provided any substantive determination in response to the Requests nor released any records responsive to the Requests within the statutory timeframe.

47. Because Defendant has not complied with the statutory time limits set forth in the FOIA statute, Plaintiff has exhausted its administrative remedies and has standing to file this action. *See* 5 U.S.C. § 552(a)(6)(C)(i).

CAUSE OF ACTION

(Violation of Freedom of Information Act)
5 U.S.C. § 552(a)

48. Plaintiff incorporates the above paragraphs as if set forth fully herein.

49. Plaintiff has a legal right under FOIA to obtain the agency records it requested in the Requests. There is no legal basis for Defendant's failure to timely respond to Plaintiff's Requests and provide Plaintiff all records responsive to the Requests.

50. Defendant FDA's failure to timely release agency records in response to Plaintiff's Requests has violated 5 U.S.C. § 552(a)(3)(A).

51. Defendant FDA has violated 5 U.S.C. § 552(a)(3)(C)-(D) by failing to make reasonable efforts to search for records responsive to Plaintiff's Requests.

52. Section 552(a)(4)(B) authorizes the grant of injunctive relief to Plaintiff because Defendant FDA continues to flout the requirements of FOIA and improperly withhold agency records. Because Defendant's refusal to respond to Plaintiff's Requests prevents Plaintiff from educating the public about the operations of the FDA and its interactions with potentially unsafe offshore manufacturers of generic drugs, Plaintiff will continue to suffer irreparable injury from Defendant's withholding of government documents subject to Plaintiff's Requests in defiance of FOIA mandates.

53. Section 2201 of Title 28 of the United States Code authorizes declaratory relief because an actual and justiciable controversy exists regarding Defendant's improper withholding of agency records in violation of FOIA.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff ProPublica respectfully requests that the Court award it the following relief:

A. Enter judgment that Defendant's unlawful withholding of the records requested violates FOIA;

B. Enter an order requiring Defendant to immediately release any and all responsive and not otherwise exempt records to Plaintiff;

C. Award Plaintiff its reasonable costs and attorneys' fees pursuant to 5 U.S.C. § 552(a)(4)(E); and

D. Grant such further relief as the Court may deem just and proper.

Dated: New York, New York
November 15, 2024

Respectfully submitted,

/s/ John M. Browning

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